

Annual List of Rulemaking Activity
Rules Adopted January 1, 2020 to December 31, 2020
Prepared by the Secretary of State pursuant to 5 MRS §8053-A sub-§5

Agency name: Department of Professional and Financial Regulation,
State Board of Nursing

Umbrella-Unit: **02-380**

Statutory authority: 32 MRS §§ 2102(D), 2104, 2153-A; 22 MRS §1812-G; and the Board's emergency rulemaking authority under 5 MRS §8054 and in response to the Governor's *Proclamation of State of Civil Emergency to Further Protect Public Health* (dated March 15, 2020) and the Governor's Executive Order 19 FY 19/20, *An Order Regarding Essential Businesses and Operations* (effective March 24, 2020).

Chapter number/title: **Ch. 5**, Regulations Relating to Training Programs and Delegation by Registered Professional Nurses of Selected Nursing Tasks to Certified Nursing Assistants

Filing number: **2020-105**

Effective date: 4/24/2020

Type of rule: Routine Technical

Emergency rule: Yes

Principal reason or purpose for rule:

State of emergency.

Basis statement:

The Maine State Board of Nursing ("Board") adopts these emergency rule changes in 02-380 CMR ch. 5, *Regulations Relating to Training Programs and Delegation by Registered Professional Nurses of Selected Nursing Tasks to Certified Nursing Assistants* pursuant to 32 MRS §§ 2102(D), 2104 and 2153-A, 22 MRS §1812-G, and the Board's emergency rulemaking authority under 5 MRS §8054 and in response to the Governor's *Proclamation of State of Civil Emergency to Further Protect Public Health* (dated March 15, 2020) and the Governor's Executive Order 19 FY 19/20, *An Order Regarding Essential Businesses and Operations* (effective March 24, 2020).

Purpose of Emergency Changes

As a result of the on-going COVID-19 public health emergency, nursing assistant students have been unable to complete the supervised clinical hours required to complete their programs and qualify for certification and listing on the Maine Registry of Certified Nursing Assistants.

Certified Nursing Assistants work in a variety of medical and long-term care facilities deemed essential under the Governor's Executive Order 19 FY 19/20, *An Order Regarding Essential Businesses and Operations* (effective March 24, 2020).

32 MRS §2102(2)(D) allows registered professional nurses to delegate selected nursing services to assistants to nurses who have completed or are currently enrolled in a course sponsored by a state-approved facility or a facility licensed by the Department of Health and Human Services but requires the Board to issue rules concerning delegation that it considers necessary to ensure quality of health care to the patient. Board rules do not currently allow registered professional nurses to delegate nursing tasks to nursing assistants who are currently enrolled in training programs.

Ch. 5 §2 of the Board's rules require nursing assistant training programs to provide 90 hours of classroom instruction, 20 hours of skills laboratory, and 70 hours of correlated, supervised clinical practice.

The emergency changes will allow nursing assistant students to obtain up to 25 hours of the necessary supervised clinical experience as paid employees of medical facilities.

Fiscal impact of rule: None.

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Umbrella-Unit: **02-380**

Statutory authority: 32 MRS §§ 2153-A(1), 2102(2-A); 32 MRS §2211(4)

Chapter number/title: **Ch. 8**, Regulations Relating to Advanced Practice
Registered Nursing

Filing number: **2020-029**

Effective date: 3/1/2020

Type of rule: Routine Technical

Emergency rule: No

Principal reason or purpose for rule:

(LD 116, SP387) *An Act Regarding Anesthesia Care in Rural Maine* (Law enacted and effective on September 12, 2017)

Basis Statement:

The amendment to ch. 8, *Regulations Relating to Advanced Practice Registered Professional Nurses*, is to address LD116, SP187, *An Act Regarding Anesthesia Care in Maine*, effective September 12, 2017. The law addresses the elimination of the certified registered nurse anesthetist's requirement to be accountable to a licensed physician or dentist in rural and critical access hospitals. The rule adds prescriptive authority to the certified registered nurse anesthetist's scope of practice in the preoperative and immediate postoperative periods. The rule clarifies the treatment and prescribing to family and friends, allows for the initial licensure of the advanced practice registered nurse that may have a degree that is more than a master's degree, reduces the continuing education requirement, and clarifies the twenty-four-month supervisory requirement.

Fiscal impact of rule:

None.

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Umbrella-Unit: **02-380**
Statutory authority: 32 MRS §§ 2153-A(1), 2102(2-C)
Chapter number/title: **Ch. 10**, Regulations Relating to Administration of Intravenous Therapy by Licensed Nurses
Filing number: **2020-030**
Effective date: 3/1/2020
Type of rule: Routine Technical
Emergency rule: No

Principal reason or purpose for rule:

Reduce the barriers for facilities to utilize licensed practical nurses to provide intravenous therapy.

Basis Statement:

The adopted language will remove the requirement of a licensed practical nurse intravenous therapy certification course approved by the Board and to allow the facilities to provide the intravenous therapy training specific to the needs of that facility.

Fiscal impact of rule:

Reduction in costs to the facility and/or licensed practical nurses to pay for a certification course.

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Umbrella-Unit: **02-380**
Statutory authority: 32 MRS §§ 2153-A, 2102(2)(C); 5 MRS §8054; Proclamation, Executive Order
Chapter number/title: **Ch. 10**, Regulations Relating to Administration of Intravenous Therapy by Licensed Practical Nurses and Registered Professional Nurses
Filing number: **2020-106**
Effective date: 4/24/2020
Type of rule: Routine Technical
Emergency rule: Yes

Principal reason or purpose for rule:

State of Emergency.

Basis Statement:

The Maine State Board of Nursing (“Board”) adopts these emergency rule changes in 02-380 CMR ch. 10, *Regulations Relating to Administration of Intravenous Therapy by Licensed Practical Nurses and Registered Professional Nurses* pursuant to 32 MRS §§ 2102(2)(C), 2153-A, and the Board’s emergency rulemaking authority under 5 MRS. §8054 and in response to the Governor’s *Proclamation of State of Civil Emergency to Further Protect Public Health* (dated March 15, 2020) and the Governor’s Executive Order 19 FY 19/20, *An Order Regarding Essential Businesses and Operations* (effective March 24, 2020).

Purpose of Emergency Changes

As a result of the on-going COVID-19 public health emergency, medical and long-term care facilities are facing nurse staffing shortages. Medical and long-term care facilities continue to operate during the public health emergency and are deemed essential under the Governor’s Executive Order 19 FY 19/20, *An Order Regarding Essential Businesses and Operations* (effective March 24, 2020).

32 MRS §2102(2)(C) allows registered professional nurses to delegate selected nursing services to licensed practical nurses when the services use standardized protocols and procedures leading to predictable outcomes in the observation and care of the ill, injured and infirm; in the maintenance of health; in action to safeguard life and health; and in the administration of medications and treatments prescribed by an individual authorized by state law to prescribe but requires the Board to issue rules concerning delegation as it considers necessary to ensure quality health care to the patient.

Ch. 10 §2(A)(1) of the Board’s rules limits a licensed practical nurse’s authorization to practice intravenous therapy administration for both Adults and Pediatrics to locations where there is on-site supervision by a registered nurse. Section 1(A)(1) of ch. 10 defines supervision to mean “that the registered nurse is on-site and immediately available to assess and evaluate nurse performance.

The emergency changes will allow licensed practical nurses to practice intravenous therapy administration in locations where a registered nurse is not on-site but is immediately available via telephone or videoconferencing technology to assess and evaluate nurse performance.

Fiscal impact of rule:

None.

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State Board of Nursing

Umbrella-Unit: **02-380**

Statutory authority: 32 MRS §§ 2102(2-A), 2152-A(1), 2210

Chapter number/title: **Ch. 12**, Joint Rule Regarding Office Based Treatment of Opioid Use Disorder (*a joint rule with 02-373 and 02-383*)

Filing number: **2020-108**

Effective date: 4/29/2020

Type of rule: Routine Technical

Emergency rule: No

Principal reason or purpose for rule:

To ensure safe and adequate treatment of opioid use disorder with approved medications in an outpatient medical setting (office-based opioid treatment).

Basis statement:

The Board of Licensure in Medicine (BOLIM) has reviewed multiple complaints and investigations regarding Maine licensed physicians providing office based opioid treatment (OBOT) raising concern surrounding knowledge of and compliance with prevailing standards of care. Due to the need for increased treatment in this State, many physicians providing OBOT in Maine have transitioned in their practice from other treatment specialties and are not experts in addiction medicine, mental health, or prescribing of buprenorphine. Deficiencies regarding OBOT noted by the BOLIM during its investigations have included:

- Inadequate facilities: lack of patient privacy; lack of appropriate facilities for urine collection.
- Inadequate medical record keeping: failure to query the prescription monitoring program (PMP); failure to document PMP checks; failure to attempt to obtain the patient's prior medical records; failure to document medical decision making.
- Inadequate or no referral to counseling and other services.
- Inadequate or no toxicological testing to confirm use of buprenorphine and exclude other non-prescribed legal and illegal substances.
- Co-prescribing buprenorphine, amphetamines, hypnotics, and benzodiazepines.
- Inadequate patient assessment for treatment needs.

Fiscal impact of rule:

(no response)

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Umbrella-Unit: **02-380**

Statutory authority: 32 MRS §§ 2102(2-A), 2153-A(1), 2210

Chapter number/title: **Ch. 21**, Use of Controlled Substances for Treatment of Pain (*a joint rule with 02-373, 02-383, and 02-396*)

Filing number: **2020-124**

Effective date: 5/27/2020

Type of rule: Routine Technical

Emergency rule: No

Principal reason or purpose for rule:

The amendments: add a table of contents to make the rule easier to use; add new definitions for "hospice services" and "terminally ill"; add section three, applicability of rule, to clarify that the rule does not apply to treatment of inpatients at medical facilities or any custodial care facility where patients do not have possession or control over their medications and medications are dispensed or administered by a licensed, certified, or registered health care provider, or to the treatment of patients who are terminally ill and who are receiving hospice services as defined by this rule; provide clarification by merging the sections for exemptions to dosage limits with exemptions to days' supply; provide clarification regarding the use of the CDC Guidelines for prescribing opioids for chronic pain; and incorporate existing continuing medical education requirements for podiatrists.

Basis statement:

This is an update to an existing joint rule (ch. 21) regarding the use of controlled substances for the treatment of pain in Maine, which consists of four sections:

Section 1 sets out the purpose of the joint rule.

Section 2 defines terms used throughout the rule.

Section 3 establishes exemptions from the rule.

Section 4 establishes principles of proper pain management, including:

- Developing and maintaining competence
- Universal precautions
- Reportable acts
- Compliance with controlled substance laws and regulations
- Compliance with CDC guideline for prescribing opioids for chronic pain

Section 5 requires continuing education regarding opioid prescribing.

The boards initiated the current rule making process following receipt of concerns from the public regarding the potentially adverse impact of the rule upon the treatment of certain patient populations. More specifically, the boards received information from the Maine Medical Association, the American Cancer Society, Home Care & Hospice Alliance of Maine, and a physician who provides hospice care expressing concerns regarding the relevance and applicability of the rule to hospice patients. In addition, the boards received information from the Maine Medical Association questioning the relevance and applicability of the rule to patients in long-term residential living facilities, and concerns regarding the existing language of the rule regarding exemptions to dosage and day limits and an apparent mandate that clinicians follow the "CDC Guideline for Prescribing Opioids for Chronic Pain- United States 2016." The boards agreed with the concerns expressed regarding the existing joint rule, and thus proposed the current amendments. Copies of the correspondence from the various entities and persons described above are attached to this basis statement and response to comments.

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The current amendments to the joint rule would:

1. Add a table of contents for better ease of use.
2. Add a definition of "Hospice Services" as defined in Title 22 MRS §8621, subsection 11 ("a range of interdisciplinary services provided on a 24-hours-a-day, 7-days-a-week basis to a person who is terminally ill and that person's family. Hospice services must be delivered in accordance with hospice philosophy.")
3. Add a definition of "Terminally Ill" as defined in Title 22 MRS §8621, subsection 17 ("a person has a limited life expectancy in the opinion of the person's primary physician or medical director.")
4. Create a new Section 3, entitled "Applicability of Rule" that would exempt patients in certain custodial care facilities and hospice care patients from the applicability of the rule as follows:

SECTION 3. APPLICABILITY OF RULE

1. Custodial Care Facilities

This rule does not apply to the treatment of patients who are in-patients of any medical facility or to the treatment of patients in any custodial care facilities (including nursing homes, rehabilitation facilities, and assisted living facilities) where the patients do not have possession or control of their medications and where the medications are dispensed or administered by a licensed, certified or registered health care provider.

2. Hospice Care

This rule does not apply to the treatment of patients who are terminally ill and who are receiving hospice services as defined by this rule.

5. Make a minor organizational change to previous Section 3(2)(e) and (f) (now Section 4(2)(e) and (f)) to clarify that the limits and the exemptions for apply to both "Dosage and Days' Supply."
6. Modify the language of previous Section 3(5) (now Section 4(5)) as follows to clarify that the clinicians should be aware of the CDC Guidelines - rather than following them verbatim - when prescribing controlled substances while treating chronic pain:

Use of the CDC Guideline for Prescribing Opioids for Chronic Pain

Clinicians are responsible for being familiar with the "CDC Guideline for Prescribing Opioids for Chronic Pain- United States 2016" (as published in the U.S. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 65, March 15, 2016.) when prescribing controlled substances for the treatment of chronic pain. Copies of the CDC guideline may be obtained at: <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> .

Fiscal impact of rule:

Minimal.